

REMARKS

This responds to the Office Action mailed on September 15, 2009.

Claims 1, 16, 30, and 35 are amended and claims 46-52 are added; as a result, claims 1-11, 14-26, 30-40, and 44-52 are now pending in this application.

New Claims

Claims 46-52 are new. Support for the new claims may be found in the specification, such as at paragraphs 0016 and 0020. Applicants believe that no new matter has been introduced in the added claims. Additionally, Applicants respectfully submit that the new claims are patentably distinct over the references currently cited as a basis of rejection, for the reasons discussed below. Accordingly, Applicants respectfully request that the Examiner consider and allow the newly added claims.

§ 112 Rejection of the Claims

Claims 1-11, 14-26, 30-40, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that the specification does not support a combination of a first layer that leaves an uninsulated region and a second layer that is not adjacent to the surface of the electrode. Applicants respectfully disagree that the specification lacks support for such language, but, solely to further prosecution, Applicants have nonetheless removed the limitation that the first layer leaves an uninsulated region from these claims.

Claims 1-11, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that it was unclear whether the first or second layer includes the pharmacological agent. Without agreeing with the Examiner, and solely to speed prosecution, Applicants have amended Claims 1-11, 14 and 15 to more clearly recite that the second layer includes the pharmacological agent.

Applicants respectfully request that these rejections be lifted.

§ 102/103 Rejection of the Claims

Claims 1-7, 9-11, 14-23, 25, 26, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (U.S. 5,551,427), or in the alternative under 35 U.S.C. 103(a) as being unpatentable in view of Altman and Bolz et al. (U.S. 5,964,794; hereinafter "Bolz").

Claims 1, 16, and 30

Altman teaches a helix constructed with a rigid core material coated with an insulative controlled release matrix. The matrix is a drug diffusion polymer system for the sustained release of drugs. The matrix can use a biodegradable polymer drug system. (See Col. 10, lines 25-34). In Figure 16, Altman disclose a cross-section view of his coating, which is a polymer matrix in which are dispersed large and small particles of drugs. The drug particles seem to be randomly distributed throughout the polymer matrix (See Fig 16).

The Examiner took the position that Altman teaches the "layers" required by Applicants' claims because the pending claims do not differentiate between "layers" and Altman's coating could be viewed as a collection of layers having arbitrary divisions. Merriam-Webster defines a "layer" as "one thickness, course, or fold laid or lying over or under another." So to have "layers," one would need to place a portion of material on top of another portion, but Altman does not teach applying more than a single layer of coating material. Altman merely teaches a single matrix layer of drug particles in a polymer and does not teach "layers."

Applicants respectfully submit that the Examiner is ignoring the plain and accepted meaning of the term "layers" and has instead interpreted that term in such a way as to render it essentially meaningless. "The protocol of giving claims their broadest reasonable interpretation during examination does not include giving claims a legally incorrect interpretation." *In re Skvorecz*, 2008-1221, pg. 8 (CAFC 2009). Applicants submit that the "layers" in the pending claims is a term that has a meaningful definition that serves to differentiate the claimed invention from the prior art teachings of a single-layer drug matrix coatings.

Furthermore, pending claims 1 and 16 have been amended to recite that the second layer is disposed over the first layer and that the third layer is disposed over the second layer. Because Altman merely teaches a matrix coat, Altman does not teach layers that are disposed one upon

the other. Applicants respectfully submit that the teachings of Altman do not anticipate the pending claims.

In the alternative, the Examiner rejected the claims as obvious in light of the combined teachings of Altman and Bolz. Specifically, the Examiner cited Bolz as teaching a drug-eluting coating that has at least four distinct layers applied in coats. The Examiner contends that it would have been obvious to one of skill to apply the coating components of Altman in layers, as taught in Bolz.

Applicants respectfully disagree. Bolz teaches an electrode coating that improves biocompatibility while simultaneously providing low electrode impedance (Col. 2, lines 7-10). Bolz's does this by using an extremely thin coating (Col. 2, lines 30-38) of one or more layers of silanes that are covalently bonded to the underlying substrate (Col. 2, lines 42-43). The layer is less than 200 nm in thickness (Col. 2, lines 26-29) which provides a coating that does not interfere with the electrical characteristics of the electrode.

As explained above, Altman teaches a drug-eluting coating that uses a matrix of polymer material that contains drug particles. The coating is attached in a traditionally mechanical way, with the electrode being dipped or sprayed with the polymer and the polymer is secured to the electrode once it is cured.

While Bolz and Altman both disclose coating systems for electrodes, their coating technologies are vastly different. Bolz is using an extremely thin coating system that use layers that are only a few atoms wide and whose thickness is measured in angstroms and nanometers, while Altman is using a coating system that uses much larger chunks of drugs that are mechanically adhered to an electrode via incorporation in a polymer matrix. Altman does not explicitly disclose how think to make his coating when applied to an electrode, but the reference he cites to as teaching his coating (US5342628) discloses diffusion testing samples that are the order of a millimeter in thickness, which is about 1 million times as thick as the coating taught by Bolz. Furthermore, Bolz is using such a molecule-wide coating system because the relatively thin coating doesn't interfere with the electrical impedance of his electrode, while Bolz does the exact opposite and uses his coating system as an insulator.

Applicants respectfully submit that one of skill in the art would not have been motivated to combine the teachings of Bolz with that of Altman because those two references teach coating

systems that are simply not analogous to one another. One of skill in the art would not have turned to the teachings of Bolz to find modifications for Altman because one of skill in the art would not have viewed the intra-molecular bonding of the Bolz coating as compatible or applicable to the mechanically-bonded coating of Altman. Also, one of skill in the art would not have turned to a coating that does not interfere with electrical impedance (e.g., the Bolz coating) to modify an electrically insulative coating (e.g., the Altman coating).

For at least these reasons, Applicants respectfully submit that the combined teachings of Bolz and Altman would not have led one of ordinary skill to the inventions of claims 1, 16, and 30. Applicants respectfully request that these rejections be lifted.

Claims 2-7, 9-11, 14, 15, 17-23, 25, 26, and 31-33

Claims 2-7, 9-11, 14, and 15 include each limitation recited in claim 1. Claims 17-23, 25, and 26 include each limitation recited in claim 16. Claims 31-33 include each limitation recited in claim 30. Thus, claims 2-7, 9-11, 14, 15, 17-23, 25, 26, and 31-33 are also not anticipated by Altman nor rendered obvious by the combined teachings of Altman and Bolz. Applicants respectfully request that these rejections be lifted.

Claims 46-50

Claims 46 and 47 include each limitation recited in claim 1. Claims 48 and 49 include each limitation recited in claim 16. Claim 50 includes each limitation recited in claim 30. Thus, claims 46-50 are also not anticipated by Altman nor rendered obvious by the combined teachings of Altman and Bolz.

§ 103 Rejection of the Claims over Altman in view of Bolz

Claims 35-37, 39, 40, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Bolz. Claim 35 is directed towards a method that includes coating an electrode with at least three layers.

As explained above, the Altman and Bolz references are non-analogous art and one of ordinary skill would not have thought to combine their teachings in order to arrive at a method

that involves applying a coating having three layers (as recited in claim 35). Claims 36, 37, 39, 40, 44, and 45 include each limitation recited in claim 35 and, thus, are also not rendered unpatentable over Altman in view of Bolz. New claims 51 and 52 also include each limitation recited in claim 35 and, thus, are also not rendered unpatentable over Altman in view of Bolz.

Applicants respectfully request that this rejection be lifted.

§ 103 Rejection of the Claims over Altman and Bolz in Further View of Benz

Claims 8, 24, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (or Altman and Bolz), as applied to claims 5, 21, and 35 above, and further in view of Benz et al. (U.S. 6,879,861; hereinafter "Benz").

As explained above, the Altman and Bolz references are non-analogous art and one of ordinary skill would not have thought to combine their teachings in order to arrive at any of the inventions of claims 1, 16, or 35. Benz does not remedy the deficiencies in either Altman and/or Bolz.

Claim 8 includes each limitation recited in claim 1. Claim 24 includes each limitation recited in claim 16. Claim 38 includes each limitation recited in claim 35. Thus, claims 8, 16, and 38 are also not rendered unpatentable over the combined teachings of Altman, Bolz and Benz.

Applicants respectfully request that this rejection be lifted.

§ 103 Rejection of the Claims over Altman and Bolz in Further View of Casa-Bejar

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (or Altman and Bolz), as applied to claim 30 above, and further in view of Casa-Bejar et al. (U.S. Publication No. 2002/0138123; hereinafter "Casa-Bejar").

As explained above, the Altman and Bolz references are non-analogous art and one of ordinary skill would not have thought to combine their teachings in order to arrive at the invention of claim 30. Casa-Bejar does not remedy the deficiencies in either Altman and/or Bolz. Claim 34 includes each limitation recited in claim 30, and, thus, claim 34 is also not rendered unpatentable over the combined teachings of Altman, Bolz and Casa-Bejar.

Applicants respectfully request that this rejection be lifted.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 15th day of February, 2010.

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